

## **Remarks/Arguments**

Claims 1-10 and 63-67 examined and rejected. By this Amendment, claims 68 and 69 are new. Accordingly, claims 1-10 and 63-69 are now pending in the application.

The additions to the claims are fully supported by the specification, the figures and the original claims. New claims 68 and 69 contain the elements in dependent claim 67 and depend from independent claims 3 and 63 respectively. Accordingly, no new matter has been added. In particular, see paragraphs [0038] and [0039] in the specification.

Reconsideration and allowance of the claims as amended is respectfully requested in view of the comments made below.

### **I. Anticipation Rejection**

Claims 1-10 and 63-67 have been rejected under 35 USC §102(b) as allegedly being anticipated by Humphrey et al. (US 5,607,401). See Office Action, p. 3.

### **Claims 1-10 and 63-66**

Independent claims 1, 3 and 63 (and claims 2-10 and 64-66 dependent thereon or having a chain of dependency thereto) cover at least a lancet device comprising a lancet having a unitary member which is hollowed along at least a portion of its length, the unitary member including a first end and a second end, wherein the first end of the unitary member is shaped to include first and second sharpened tips; and a lancet holder arranged and configured to hold the second end of the lancet and move the lancet to penetrate the skin of a patient with the first and second sharpened tips.

In the Office Action, the Examiner characterizes Humphrey's hypodermic cylindrical needle (Fig. 12) attached to a syringe (Fig. 58) as capable to use as a lancet and a lancet device. However, Humphrey clearly distinguishes throughout the patent the differences between a lancet and a needle. Humphrey discloses flexible polymeric

piercing members in two broad classes: a solid lancet or a needle with at least one lumen. (Col. 6, lines 59-63). Therefore, Humphrey does not disclose or teach a lancet which is hollowed along at least a portion of its length.

Humphrey discloses an augmenting means that makes it possible for the flexible, polymeric lancet to pierce the skin, a function that the lancet would otherwise be unable to do unaided. (Col. 7, lines 52-57; col. 8, lines 49-53). Therefore, Humphrey does not disclose or teach a lancet having a unitary member. Applicant respectfully submits that the solid lancet 40 with augmenting means 42, 44 and supporting base structure 48 that comprise the piercing member of Humphrey is not a lancet having a unitary member which is hollowed along at least a portion of its length.

The Examiner characterizes Humphrey's first end as having first and second sharpened tips that are created by a pair of bevel or planar faces. Humphrey teaches that for a lancet 40, the tips shown in Figs. 18 or 19 can be used. (Col. 8, lines 11-14; col. 10, lines 4-5 and 40-45; col. 12, lines 5-9 and 59-62). Both Figs. 18 and 19 illustrate a lancet with one sharpened tip. Therefore, Humphrey does not disclose or teach a lancet with a first end having first and second sharpened tips that are created by a pair of bevel or planar faces.

Moreover, Humphrey does not render obvious the lancet having a unitary member with two sharp tips. The Examiner characterizes Humphrey as disclosing a needle point that includes the first and second ground surfaces, shown in Fig. 12. The Examiner fails to recognize that Humphrey is not referring to a lancet, but only to a needle. Humphrey teaches that "the polymeric hypodermic needle version" it discloses may be used with a tip shown in Figs. 11-17. (Col. 9, lines 54-62; col. 10, lines 55-56; col. 12, lines 9-12). Humphrey clearly distinguishes between needles and lancets, thereby teaching away from the use of a double tip with a lancet.

**Claim 67 (and new claims 68 and 69)**

Claims 67-69 cover the independent base claims from which they depend as argued above as well as a rigid unitary member.

By contrast, Humphrey discloses polymeric hypodermic devices which use a flexible piercing member. (Col. 6, lines 51-52). The piercing member is made of plastic. (Col. 6, lines 64-66). The flexible piercing members require separate augmenting means in order to perform the piercing process. (Col. 6, lines 43-45; col. 7, lines 9-10 and lines 54-57; col. 8, lines 49-53). Accordingly, Humphrey does not disclose, teach or suggest the rigid unitary member of claims 67-69.

**II. Obviousness Rejections**

Claims 1-10 and 63-67 are rejected as allegedly being obvious under 35 USC §103(a) over Ayres (US 3,906,932), in view of Boothroyd (Geoffrey Boothroyd, Peter Dewhurst, Winston Knight, Product Design for Manufacture and Assembly, 1994, Marcel Dekker, Inc. pages 64 and 165). See Office Action, p. 5.

Independent claims 1, 3 and 63 (and claims 2-10 and 64-69 dependent thereon or having a chain of dependency thereto) cover at least a lancet device comprising a lancet having a unitary member which is hollowed along at least a portion of its length, the unitary member including a first end and a second end, wherein the first end of the unitary member is shaped to include first and second sharpened tips; and a lancet holder arranged and configured to hold the second end of the lancet and move the lancet to penetrate the skin of a patient with the first and second sharpened tips.

The Examiner contends that Ayres discloses the limitations of the independent claims 1, 3 and 63 but fails to disclose both ends of the needle 40 having the same needle point design. The Examiner contends that the teaching by the Boothroyd reference of the benefits of symmetrical design would render the claims obvious because one of ordinary skill in the art would use the tip of Ayres on both ends to achieve the same advantages. (O.A., pg. 6).

The Examiner has failed to make a *prima facie* case of obviousness. The needle in Ayres was designed to penetrate the rubber stopper of a Vacutainer. The needle in Ayres addressed the problems of needle deflection when entering the stopper and coring of the stopper. (Abstract, Col. 1, lines 36-50). To avoid deflection and coring, Ayres teaches bending the sharp tips of the needle inward in abutting relationship, as shown in Figs. 2, 4 and 8. (Col. 2, lines 30-35). There is no teaching, suggestion or motivation to apply the abutting tips of Ayres to a lancet that penetrates skin. As a matter of fact, the configuration of the needle tip of Ayres would inhibit blood flow and likely be more painful to the patient. One skilled in the art would not look to the design of a needle designed to penetrate rubber as a basis for penetrating human skin.

Combining Ayres with Boothroyd, for the sake of argument, might teach a needle with the same Vacutainer tip configuration of Ayres on each end of the needle. However, this design again would in no way alleviate the problems of sufficient blood and minimal pain that Applicants are addressing. It is not clear to Applicant how teaching a needle with symmetrical ends having the vacutainer needle design taught in Ayres would render obvious a skin-penetrating lancet having a first end with the first and second sharpened tips disclosed by Applicants.

Boothroyd is non-analogous art even in light of KSR. As the Examiner states, Boothroyd discloses that for ease of handling an assembly component during an assembly process, the assembly components should be designed to have end-to-end symmetry. This symmetry helps prevent jamming or tangling when components are stored in bulk. (Pg. 64). Boothroyd also indicates that such design considerations are vital to high-speed automatic and robot assembly. (Pg. 165). The Boothroyd reference is not analogous art as it is not from the field of lancets or any related medical device field, is not reasonably pertinent to the problems addressed by the invention as Boothroyd does not address blood flow and patient pain, and logically would not have commended itself to an inventor's attention in considering the problems because of the matter with which Boothroyd deals, namely decreasing problems with automated


assembly systems. In addition, the level of ordinary skill in the pertinent art of lancet design is different than the level of ordinary skill in the art of designing for ease of automatic assembly processes. Therefore, the combination of Ayres with the Boothroyd reference does not render the claims obvious.

For these reasons at least, the combination of Ayres and Boothroyd does not teach, suggest or render obvious claims 1-10 and 63-69.

For the reasons set forth above, Applicant traverses the Examiner's rejections and respectfully submits that all pending claims are allowable. Applicant requests the Examiner's early examination of the pending claims in the present application. In the event that the Examiner deems a telephonic discussion would be helpful in advancing the prosecution of the present application, Applicants respectfully request the Examiner to contact Applicants' representative at (248) 244-0163.

Respectfully submitted,

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